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Dockets Management Branch
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20857

Citizen Petition

Dear Sir/Madam:

The undersigned respectfully submit this petition under Section 505(j) of the Federal Food, Drug and Cosmetic Act (the "Act") and Section 10.25 of FDA's regulations on behalf ofa client.

A. Action Requested

This petition requests that the Commissioner adopt a policy under which the 180-day exclusivity period that must expire before approval of a subsequent abbreviated new drug application may be made effective (pursuant to §505(j)(5)(B)(iv) of the Act) will apply to all strengths of a listed reference drug which contain the same active ingredient or ingredients, the same indications and directions for use and for which the same patents are listed pursuant to $314.53 of FDA's regulations.

The requested policy would apply only in situations in which(1) the first ANDA to be submitted containing a paragraph IV certification is substantially complete for at least one

strength of the reference listed drug; (2) the applicant is sued in an action initiated as provided by $505(j) (5)(B)(iii); and (3) all patents listed for the reference drug are found to be invalid or unenforceable by a court in a final judgment from which no appeal can be or has been taken (21 C.F.R. §3 14.107(e)).[1] If all three of these conditions are not met, exclusivity would be granted in accordance with present FDA policy providing for "split exclusivity" for different strengths in specified circumstances.

If the requested policy is adopted, when a final judgment is entered that the listed patents are invalid or unenforceable, the successful first ANDA applicant would receive the 180-day period of exclusivity upon effective approval of those dosage strengths included in its ANDA which are found by the FDA to be equivalent to the corresponding dosage strengths of the reference drug. During that exclusivity period no effective approvals of

[1] If more than one patent is listed for the reference drug, a judgment of invalidity or non-enforceability must issue for all patents that are in force at the time of the judgment and for which the ANDA applicant had filed a paragraph IV certification claiming invalidity or non-enforceability.

other strengths of the reference listed drug would be granted to any other applicant.[2] Subsequent ANDAs citing to the reference listed drug could be made effective for the same or other strengths only after the expiration of the first applicant's 180-day exclusivity in accordance with $505(j)(5)(B)(iv).

Adoption of the advocated policy would not infringe any rights of the holder of the reference new drug application or the patent holders or any other prospective ANDA applicant. This situation is distinguishable from the FDA's policy of December 4, 1998, discussed below, which involved non-infringement challenges by the first applicant, and indeed all applicants, rather than challenges based on invalidity or non-enforceability. The policy now proposed would permit earlier eligibility for approval and market availability under "subsequent" ANDAs by reason of permitting immediate effective approval of ANDAs for every qualified strength of the reference drug after expiration of the 180-day exclusivity period awarded to the first applicant and without requiring meaningless Paragraph IV challenges to patents that have already been found invalid or unenforceable.

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[2] If the first court finding of invalidity or non-enforceability were made in a case decided before the first applicant's case, the statutory 180-day exclusivity period might commence before the first applicant received effective approval to market its product. 21 C.F.R. $314.107(c). However, the exclusivity would be the property of the first applicant and could not be utilized by any other applicant with a tentatively-approved application unless marketing rights to this exclusivity were granted to it by the first applicant. Under the requested policy, judgments of non-infringement (as distinct from judgments of invalidity or unenforceability) in cases brought against subsequent applicants and decided prior to the first applicant's case would not provide any subsequent applicant with entitlement to exclusivity as to any strength of the reference drug, even if the first applicant had not applied for that strength.

B. Statement of Grounds

On December 4, 1998, FDA rendered its decision on the TorPharm citizen petition filed on July 2, 1998, Docket 98P-0547. That petition raised the question whether there was an entitlement to 180-day exclusivity for a recently approved 75 mg. strength of ranitidine hydrochloride even though such exclusivity had previously been granted and expired as to other strengths of ranitidine hydrochloride.

The very same patents were applicable to the 75 mg. strength as to the earlier approved strengths, but the FDA reasoned that the result of patent infringement litigation as to one strength may not be applicable to another strength of the same drug because varying formulations of differing strengths may provide separate and distinct bases for patent challenges. Specifically, it reasoned that the findings of non-infringement as to the earlier approved strengths did not necessarily preclude the possibility of infringement for other strengths of the drug.

Petitioners submit that while there may be a basis for FDA to claim that issues in a patent litigation case as to one strength are not applicable to other strengths in situations in which patent "non-infringement" alone is found, this is not so if the patents are found to be "invalid" or "unenforceable." In a situation in which the patents are found to be invalid or unenforceable in litigation involving one strength of a drug, it is equally invalid or unenforceable as to any other strength of that drug. There is not even a theoretical basis to assert that a finding of invalidity or unenforceability of the applicable patents would not apply to a subsequent applicant for another strength of the drug.

The first applicant to submit a substantially complete ANDA with a paragraph IV certification and who succeeds in litigation which invalidates the applicable patents, or in which they are found unenforceable, has accomplished the complete task of nullifying those patents as a barrier to competition. It follows from the Congressional intent underlying the 180-day exclusivity period that the successful initial paragraph IV applicant should be the only one to benefit from doing so. But applying the conclusion FDA reached in Docket No. 98P-0547 to situations in which patents are found to be invalid or not enforceable, rather than only not infringed, would permit the holder of the reference drug whose protection has been defeated to continue to maintain market exclusivity for all strengths for which the FDA would continue to require paragraph IV certification. While the first applicant with the paragraph IV certification who obtained a judgment of invalidity or unenforceability would, by application of the principle ofres adjudicate, be freed of meaningful risk of facing another action by the patent holder and obtain effective approval of all other strengths of the reference drug when the scientific criteria for approval were satisfied, other applicants would still have to follow the paragraph IV procedure.

Petitioners recognize that the mere assertion of invalidity or unenforceability in a paragraph IV certification by the first applicant cannot be the basis for a subsequent applicant to claim that a patent has in fact been invalidated or rendered unenforceable. If that first applicant is not sued, subsequent applicants for other strengths of the reference drug might still be successfully sued under patents for which the first applicant was not charged with violations. However, under the policy requested in the petition, if the first applicant is sued

and is successful in obtaining a final judgment of invalidity or unenforceability of all applicable patents, at the expiration of the first applicant's 180-day exclusivity period the way would have been opened for subsequent applicants as well to obtain effective approval for all strengths of the drug so long as their scientific data are adequate.

On the basis of the above argument, petitioners now propose a limited exception to FDA's determination in Docket No. 98P-0547 for situations in which the initial applicant with a paragraph IV certification certifies that the applicable patents are invalid or unenforceable and is subsequently sued. In those situations, no effective approvals would be granted for any strength of the listed drug until the first applicant's case goes to final judgment.[3] If the final, non-appealable judgment is that the patent involved is invalid or unenforceable, the first applicant would be granted 180-day exclusivity for those strengths of the listed drug for which it has satisfied the standards for approval.[4] No other applicant would thereafter qualify for any exclusivist y for any strength of that listed drug, and all applicants having tentative approval could obtain effective approval for all strengths as soon as the first applicant's 180-day exclusivity has run out.

The appropriate resolution of the issue, consistent with the intent of the 180-day exclusivity provision in the statute, is derived from the validity or enforceability of the

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[3] Or until the patents involved were adjudged invalid or unenforceable in another case reaching a final judgment prior to the first applicant's case. This would trigger the first applicant's exclusivity even though no final judgment had been entered in its case.

[4] As stated above, if no such judgment were reached or if the first applicant were not sued, exclusivity would be granted in accord with present FDA policy allowing for "split exclusivity" for different strengths in appropriate circumstances.

patents listed for the reference drug. Iftherelevant patents aredefeatedbythe first applicant who makes a paragraph IV certification and who submits a substantially complete ANDA, all dosage strengths listed for those patents in the reference NDA should become open to other applicants after expiration of the 180-day exclusivity period granted to the prevailing applicant's ANDA.

Both Congress and the FDA have recognized that there should be no more than one victor of the 180-day exclusivity prize per product. If an applicant for an ANDA of one strength of a multi-strength reference drug prevails in patent litigation on the basis of invalidity or unenforceability, patent protection is lost for all of the strengths to which the patents were claimed to apply and the market opened as to each of those dosage strengths. It is for this accomplishment that the 180-day exclusivity is awarded. FDA recognized this in its July 29, 1988 letter to NDA or ANDA Holders and Applicants concerning the 180-day exclusivity provision. There it stated:

> "section 505(j) (4)(B)(iv) may be interpreted as providing a reward to the applicant who benefits the public by challenging a patent and allowing competition"

As the quoted statement indicates, the "reward" to the public for a successful challenge to a patent as invalid or unenforceable would provide an earlier potential for all dosage strengths of the reference drug to be made available upon the expiration of a single 180-day exclusivity period, rather than the multiple exclusivity periods that would result from the FDA's determination.

C. Environmental Impact

Categorical exclusion is claimed under Section 25.30(h) of the regulations.

D. Economic Impact

Economic information will be submitted if requested by the Commissioner.

E. Certification

The undersigned certifies that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioners which are unfavorable to the petition.

Respectfully submitted,

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Richard S. Morey

AHK:RSM/sdj